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Attorneys for Defendant Wyeth Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JOSEPH W. DYKSTRA,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC.,

Defendant.

Case No. 08-CIV-7432(CS)(GAY)

DECLARATION OF JAMES H.
McQUADE IN SUPPORT OF
DEFENDANT'S MOTION TO
DISMISS

I, James H. McQuade, declare:

- 1. I am an attorney admitted to practice before this Court and am employed by Orrick, Herrington & Sutcliffe LLP, counsel for Defendant Wyeth Pharmaceuticals, Inc. ("Defendant") in the above-entitled action. I submit this Declaration in support of Defendant's motion to dismiss, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.
- 2. Attached hereto as Exhibit 1 is a true and correct copy of the Verified Complaint filed by Joseph Dykstra in the Supreme Court of the State of New York, County of Rockland, on or about June 6, 2008. On August 22, 2008, within 30 days after receiving a copy

of the Complaint, Defendant removed the action to this Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 29, 2008 at New York, New York.

OHS East: 160472327.1

Exhibit 1

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF ROCKLAND

JOSEPH W. DYKSTRA,

Plaintiff,

Index # SU - 2008 - OS479
Date Purchased: 06/06/2008

-against-

VERIFIED COMPLAINT

WYETH PHARMACEUTICALS, INC.,

Defendant.

Plaintiff designates Rockland County as the place of trial The basis of venue is CPLR Sec. 503 (a)

X-----

The Plaintiff, JOSEPH W. DYKSTRA, by his attorney, Barry D. Haberman, Esq., complaining of the Defendant, WYETH PHARMACEUTICALS, INC., respectfully alleges as follows:

- The Plaintiff, Joseph W. Dykstra, herein referred to as "Dykstra", is a New York resident, domiciled at 1003 Chestnut Ridge Road, Chestnut Ridge, New York 10977, in Rockland County, New York.
- Said domicile of Plaintiff, "Dykstra", is located in the jurisdiction of the
 Supreme Court of the State of New York, Rockland County.
- 3. Upon information and belief, Defendant, Wyeth Pharmaceuticals, Inc.., herein referred to as "Wyeth", is a foreign Corporation, authorized to conduct business in the State of New York with offices located at 401 North Middletown Road, Pearl River New York, in Rockland County.

AS AND FOR A FIRST CAUSE OF ACTION

4. The Plaintiff, "Dykstra", repeats and reiterates each and every allegation hereinbefore set forth, with the same force and effect as if set forth herein.

- 5. Upon information and belief, the Plaintiff, "Dykstra" was hired by the Defendant, "Wyeth" on or about November 30, 1992.
- 6. Upon information and belief, said Plaintiff, "Dykstra" was employed continuously by the "Defendant, "Wyeth" from 1992 through the termination of his employment on or about June 11, 2007.
- 7. At the time of the termination of the Plaintiff, "Dykstra's" employment, he his position of employment was asceptic setup worker.
- 8. Upon information and belief, the Plaintiff, "Dykstra", was a satisfactory employee for the "Defendant, "Wyeth", for the entire term of his employment, 14 plus years.
- 9. Upon information and belief, the Defendant, "Wythe" is the pharmaceutical business, and said business involves developing, testing, manufacturing and distribution of pharmaceutical products.
- 10. Upon information and belief, the above mentioned activities of Defendant, "Wyeth" are regulated by various governmental agencies, including but not limited to the Federal and Drug Administration ("FDA") and the Occupational Safety and Health Administration ("OSHA").
- 11. Upon information and belief, the Defendant, "Wyeth" is subject to the provisions 21 CFR sec. 600.14 as published by the FDA, governing conduct of a manufacturer licensed biological products.
- 12. Upon information and belief, pursuant to CFR sec. 600.14, the Defendant, "Wyeth" is required to report to the Center of Biologics Evaluation and Research and the Office of Compliance and Biologics Quality within 45 days of any event associated with

the manufacturing, which includes testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product, in which the safety, purity, or potency of a distributed product may be affected.

- 13. Upon information and belief, such regulation was issued by the FDA in order to prevent substantial and specific danger to the public health or safety.
- 14. Upon information and belief in late February or early March 2007, the Plaintiff, "Dykstra" witnessed a violation of standard operating procedures of the Defendant, "Wyeth."
- 15. Upon information and belief, at the time referenced in paragraph 14 above, four (4) individuals employed by the Defendant, "Wyeth" performing maintenance tasks in a room designated for a clean environment had failed to perform a specific task called "plating" which is done to ensure that cleanliness of the room (sterile and sanitized) was maintained. The failure to "plate" was a violation of the Defendant's Standard Operating Procedure ("SOP") designed to ensure safety of the produce.
- 16. The Plaintiff, "Dykstra" was informed by these individuals that they were instructed not sign in. (This too is a violation of the Defendant's SOP.)
- 17. Upon information and belief, two of the individuals performing work in the clean room were not certified for such duties. This is yet again another violation of the Defendant's SOP.
- 18. Upon information and belief, work that was performed by individuals not certified to be performing activities in a clean environment constitutes a destruction of a controlled environment, as stated in the Defendant's SOP.

- 19. Upon information and belief, once there was a destruction of a controlled environment, the Defendant was required to perform a "triple cleaning" to ensure the reestablishment of the controlled environment. This is required by the Defendant's SOP.
- 20. Upon information and belief, the required "triple cleaning" was never performed, such that a controlled environment was not properly established.
- 21. Upon information and belief, manufacturing of product continued in the compromised room, an act which is yet again a violation of the Defendant's SOP.
- 22. The Plaintiff, "Dykstra" reported the violation of the Defendant's SOP to his supervisor, Humberto Zayas on the same day that he witnessed said violation.
- 23. The room in question was used by the Defendant, "Wyeth" for the manufacture of a vaccine given to children between the ages of 6 weeks and 10 years. Said vaccine is "Prevnar", which is given to prevent pneumococcal bacteria that can cause serious diseases such as meningitis (an infection of the covering of the brain and spinal cord) and bacteremia (an infection of the blood).
- 24. As such, the environment in the room of manufacture is an act which the FDA monitors.
- 25. Upon information and belief, the Defendant, "Wyeth" was required to report to the event to the FDA, as said event qualifies as an event in which in safety, purity, or potency of a distributed product may be affected.
- 26. Upon information and belief, as stated above, the Defendant, "Wyeth" failed to report the event described above to the FDA.
- 27. The failure of the Defendant to report the event to the FDA is an act which is a substantial and specific danger to the public health or safety.

- 28. The acts of the Defendant, "Wyeth" are violations of 21 CFR sec. 600.14.
- 29. As stated above, the Plaintiff, "Dykstra" notified his supervisor, Humberto Zayas of the violation. However, instead of reporting the violation as required to the FDA, the Defendant, "Wyeth" terminated the employment of the Plaintiff.
- 30. The Plaintiff, "Dykstra" asserts that the termination was not for a valid reason, but was pretextual in nature, that is for the sole reason of the Plaintiff's reporting of a violation of rule or regulation which would have a substantial and specific danger to the public health or safety.
- 31. The act of terminating the Plaintiff's employment for reporting said event is retaliation as defined by New York LL sec. 740(1)(e).
- 32. The act of terminating the Plaintiff's employment for reporting said event is prohibited by New York LL sec. 740(2)(a) and (c).
- 33. Pursuant to New York LL sec. 740(5) the Plaintiff is entitled to (b) reinstatement to his position of employment; (c) reinstatement of full fringe benefits; (d) compensation for lost wages, benefits and other remuneration; and (e) reasonable costs, disbursements and attorney's fees.
- 34. The Plaintiff seeks reinstatement to his position of employment, monetary damages incurred since the Defendant ceased compensation, reinstatement of full fringe benefits, reasonable costs, disbursements and attorney fees.
- 35. As the Plaintiff earned \$1,722.96 per week, the Plaintiff seeks same as compensation since the date that the Defendant ceased paying wages.

36. Thus, there is now due and owing from the Defendant to the Plaintiff the sum of \$1,722.96 per week for each week since the date that the Defendant ceased paying wages to the Plaintiff.

WHEREFORE, the Plaintiff, Joseph W. Dykstra, demands judgment:

- (1) Against the Defendant, for termination of his employment in violation of the Plaintiff, "Dykstra's" rights under the provisions of New York State Labor Law, sec. 740 et. seq., "New York's Whistleblower Protection Act".
- (2) Against the Defendant, reinstating the Plaintiff, "Dykstra" to his position of employment; reinstatement of full fringe benefits; awarding the Plaintiff, "Dykstra", back pay in the amount of \$1,722.96 per week for each week since the date that the Defendant ceased paying wages; and costs, disbursements and attorney fees, the remedy provided a Plaintiff under the provisions of New York State Labor Law, sec. 740 et. seq.

Dated: New City, New York June 6, 2008

> BARRY D. HABERMAN, ESQ. ATTORNEY FOR PLAINTIFF JOSEPH W. DYKSTRA 254 SOUTH MAIN STREET #401 NEW CITY, NEW YORK 10956 845-638-4294

VERIFICATION

That the deponent, JOSEPH W. DYKSTRA, is the Plaintiff, in the within action; that deponent has read the foregoing and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matters therein stated to be alleged upon information and belief; and as to those matters, deponent believes them to be true.

The grounds for deponent's belief as to all matters not stated upon his knowledge are investigations which he has made or has caused to be made concerning the subject matter of this action, and statements of parties and/or witnesses made herein.

The undersigned affirms that the foregoing statements are true.

Dated: New City, New York June 6, 2008

JOSEPH W. DYKSTRA

IN PRESENCE OF

STATE OF NEW YORK

COUNTY OF ROCKLAND)

On the day of June 2008, before me, the undersigned, a Notary Public in and for said State, personally appeared JOSEPH W. DYKSTRA, personally known to me or proved to me on the basis of satisfactory evidence, to be the individual whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument, the individual or person upon behalf of which the individual(s) acted, executed the instrument.

Notary Jublic

BARRY D. HABERMAN Notary Public, State Of New York No. 02HA6057921 Qualified in Rockland County \ Commission Expires 04/30/200